REMARKS

Claims 19-31 are currently pending in the application. Claims 19 is withdrawn. Claim 20 is amended to correct an obvious typographical error, which one of ordinary skill in the art would have understood. No new matter is added.

Information Disclosure Statement

Applicants request entry of the references cited in the Information Disclosure Statement filed February 20, 2004.

An Information Disclosure Statement was mailed to the Office on January 30, 2002, with a form PTO-1449 of 6 pages. In the copy of this PTO-1449 mailed with the present office action, the entries of U.S. patent documents (pages 1-3) have been initialed by the examiner, but not the entries for the foreign patent documents (pages 3-4) or the non-patent documents (pages 4-6). A copy of this Information Disclosure Statement is provided herewith as Exhibit A.

All of the references in that Information Disclosure Statement were also cited in parent application 08/993,586, now U.S. Pat. No. 6,251,418. The Information Disclosure Statement filed in the patent application was filed in accordance with 37 C.F.R. § 1.98(a)-(c), and the present application is a divisional of that patent. Under 37 C.F.R. § 1.98(d), applicants are therefore not required to submit copies of the references cited in the Information Disclosure Statement of January 30, 2002.

Applicants respectfully request entry and consideration of the foreign patent documents and the non-patent documents in the present application. Alternatively, copies of the references can be sent upon the examiner's request.

Restriction Requirement

In a telephonic interview between the examiner and Mr. John Perullo, the delivery device of claims 20-31 was provisionally elected for prosecution. A species election was also required, between either the species shown in Figs. 2A, 2B and 4A, or the species shown in Figs. 3A, 3B and 4B, and a statement of the claims readable on the elected species was required with the election. The species depicted in Figs. 2A, 2B and 4A was provisionally elected, pending a more

careful study of these figures and the claims. Mr. Perullo specifically reserved the right to traverse the requirement for restriction and species election.

Applicants now elect the delivery device of claims 20-31 for prosecution, and the species depicted in Figs. 2A, 2B and 4A. Applicants also traverse the requirement for species election.

Elected claims 20-31 are directed to an apparatus for implanting a therapeutic agent within a tissue wall. The claim to the pellet to be implanted within the tissue wall (claim 19) was not elected for prosecution. Study of the elected apparatus claims reveals that the apparatus does not have a structure specifically designed to accommodate the shape of the pellet. Claims 20-31 are therefore all readable on a delivery device delivering the pellets depicted in Figs. 2A, 2B and 4A. Claims 20-31 are also readable on the pellet species depicted in Figs. 3A, 3B and 4B.

Study of the apparatus of Figs. 2A and 3A also shows an apparatus that is interchangeable between the two pellet types. That is, the apparatus of Fig. 2A could be used to deliver the pellet of Fig. 4B, and the apparatus of Fig. 3A could be used to deliver the pellet of 2B. Applicants therefore respectfully submit that the species requirement is improper.

The office action states that claims 20-23, 26 and 29-30 are generic. Applicants respectfully submit that claims 25, and 27-28 should also be considered generic. Claim 25 discloses an apparatus with a pointed distal end, which can be used with either type of pellet. Claim 27 discloses a ratchet assembly for allowing delivery of discreet amounts of the therapeutic agent, and claim 28 discloses a threaded plunger for advancing into the delivery chamber responsive to a rotating action. The apparatus of both of these claims could also be used in delivering either type of pellet. These claims should therefore also be considered generic with respect to the type of pellet being delivered.

Withdrawal of the requirement of species election would require no additional searching, because the apparatus of claims 20-31 can be used with either type of pellet, and because a search on the apparatus will include art covering therapeutic agents in a variety of forms.

Applicants' Invention

Applicants' invention is an apparatus for implanting a therapeutic agent within a tissue wall. It includes an elongate flexible body, a delivery chamber coupled to the distal end and

having a space for carrying the therapeutic agent, and a port for releasing the therapeutic agent. It also includes an actuator coupled to the delivery chamber and capable of driving the therapeutic agent through the port. The distal end can be adapted to penetrate a tissue wall so that the therapeutic agent can be delivered within the tissue wall.

The apparatus can also includes a control mechanism coupled to the actuator, which provides control of the actuator, and a steering mechanism for turning the distal end of the apparatus, allowing the user to selectively guide the device through a body lumen. It can also include a lever-action handle coupled to the control mechanism.

The distal end can be dimensionally adapted to allow for transluminal delivery entry into the interior of a patient's heart. It can also include a plunger for driving the therapeutic agent from the delivery chamber, such as a threaded plunger for advancing into the delivery chamber in response to a rotating action, and a ratchet assembly for allowing delivery of the therapeutic agent in discrete amounts.

The delivery chamber can be substantially cylindrical, and adapted to receive and store the therapeutic agent in the form of a pellet, for instance, a minisphere.

Lemelson (U.S. Pat. No. 4,588,395)

U.S. Pat. No. 4,588,395 to Lemelson ("Lemelson") discloses a device for disposing material at a "select location" within the body. The material is retained within a housing which is located at the end of a flexible tube or catheter, which is inserted into a body cavity. The device is extended through a body lumen to the desired location, and the material is then expelled from the device by advancing a shaft.

There is no mention of the device being capable of implanting the material within a tissue wall.

Matsuno *et al.* (U.S. Pat. No. 5,342,394)

U.S. Pat. No. 5,342,394 to Matsuno *et al.* ("Matsuno") discloses an apparatus for blocking a vein branch. It has an outer tube, an inner tube, a push-out member within the inner tube which pushes out a blocking member, which blocks the vein.

Matsuno does not teach or suggest the implantation of a therapeutic agent within a tissue wall.

Leschinsky (U.S. Pat. No. 5,873,499)

U.S. Pat. No. 5,873,499 to Leschinsky *et al.* ("Leschinsky") discloses a device in a "gun" form, for dispensing a measured amount of fluid.

Leschinsky does not teach the implantation of an agent within a tissue wall.

Claim Rejections Under 35 U.S.C. § 102

Claims 20-21, 23-24, 26 and 29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lemelson. The office action states that this reference discloses an elongate flexible body, a delivery chamber with a space and a port, an actuator, a control mechanism and a plunger.

The office action also states that the Lemelson device is intended to be used in arteries, "therefore, its diameter is dimensioned small enough to traverse the vessels leading from the heart of a patient thereby making it small enough to enter the larger atrium and/or ventricles of the heart."

Lemelson does not teach or suggest that the device can be used to deposit the material into a tissue wall, as is required by applicants' claims. In fact, column 3, lines 37-42 state that the flexible shaft pushes the material out, causing it to protrude from the end of the device, "or to eject it completely therefrom so that it lies against the tissue adjacent the end of the catheter" (emphasis added). In contrast applicants' claims state that therapeutic agent is implanted within a tissue wall. If applicants' claimed apparatus, as shown in Fig. 5 for example, were to eject the therapeutic agent as disclosed in Lemelson so that the ageny lay against the myocardium, the agent would be swept away in the bloodstream, and would fail to be implanted within the tissue wall.

Lemelson therefore fails to anticipate the subject matter of applicants' claims, and the rejection on this basis should be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claim 22 was rejected as unpatentable in view of Lemelson and Matsuno, and claims 27-28 and 30 were rejected as unpatentable in view of Lemelson and Leschinsky.

The office action states that Matsuno provides a steering mechanism (part number 31 in Fig. 9), and that it would have been obvious to combine the steering device of Matsuno with the device of Lemelson. Leschinsky is stated to disclose a dispensing gun that includes a plunger that can be threaded, notched or grooved, and also includes a handle with a trigger and a pawl.

The addition of either Matsuno or Leschinsky does not cure the deficiency in Lemelson as discussed above. Like Lemelson, neither Matsuno nor Leschinsky teach or suggest the implantation of a therapeutic agent within a tissue wall. The combination of these references creates an improved, steerable version of the Lemelson device, in which the therapeutic agent is deposited within a body lumen, not within a tissue wall.

For this reason, applicants respectfully request that the rejections on this basis be reconsidered and withdrawn.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

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